



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/634,331	08/04/2003	Alan J. Polito	064881-5005 US-03	6774
43850	7590	05/25/2006	EXAMINER	
MORGAN, LEWIS & BOCKIUS LLP (SF) 2 PALO ALTO SQUARE 3000 El Camino Real, Suite 700 PALO ALTO, CA 94306			HINES, JANA A	
			ART UNIT	PAPER NUMBER
			1645	

DATE MAILED: 05/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/634,331	<b>Applicant(s)</b> POLITO ET AL.	
	<b>Examiner</b> Ja-Na Hines	<b>Art Unit</b> 1645	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 13 March 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 98,99 and 101-116 is/are pending in the application.
- 4a) Of the above claim(s) 107-116 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 98,99 and 101-106 is/are rejected.
- 7) ☐ Claim(s) 102-106 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on March 13, 2006 has been entered.

### ***Amendment Entry***

2. The amendment entered March 2, 2006 has been previously entered. Claims 98-99 have been amended. Claims 1-97 and 100 have been cancelled. Claims 107-116 have been withdrawn from consideration. Claims 98, 99 and 101-106 are under consideration in this office action.

### ***Withdrawal of Rejections***

3. The following objections and rejections have been withdrawn in view of applicants' amendments and arguments:

- a) The objection of claim 100;
- b) The rejection of claims 98-106 under 35 U.S.C. 112, second paragraph; and
- c) The new matter rejection of claims 98-106 under 35 U.S.C. 112, first paragraph.

***Response to Arguments***

4. Applicant's arguments filed March 2, 2006 have been fully considered but they are not persuasive. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

***Claim Rejections - 35 USC § 102***

5. The rejection of claims <sup>98,99,101-106</sup> under 35 U.S.C. 102(b) as being anticipated by Zweig (US Patent 5,554,531) is maintained for reasons already of record. The rejection was on the grounds that Zweig teaches an apparatus comprising a housing; an autostart means; heating element; and test strip.

Applicants' assert that Zweig lacks any recitation of an apparatus wherein the autostart means comprises a capacitance sensor. As applicants' state in their response, a capacitor consists of two conducting plates which could be of any shape or size separated by an insulating material called a dielectric or dielectric layer. Zweig teaches two spaced apart plates composed of conductive material. This conductive material meets the limitations of a dielectric layer. Therefore the plates of Zweig meet the limitations of the capacitor plates of the instant application. Thus, applicants' arguments about measuring electrical resistance versus measuring capacitance are not persuasive, since there is no structural difference between spaced apart conductive plates which have the ability to measure either resistance or capacitance. There must be a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. Since the prior art

structure is capable of performing the intended use, it meets the claim. Therefore contrary to applicants' assertions, Zweig meets the limitations of the claims and applicants' arguments are not persuasive.

In response to applicant's arguments, the recitation of an apparatus useful for detecting the addition of a sample to a test strip in a lateral flow assay has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951). Furthermore, in response to applicant's argument that the apparatus is useful for detecting the addition of a sample to a test strip in a lateral flow assay, it is noted that this recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. Therefore, applicants' assertions are not persuasive and the rejection is maintained.

#### ***Double Patenting***

6. The rejection of claims <sup>98, 99, 101-106</sup> 101-106 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over U.S. Patent

Art Unit: 1645

No.6,136,610 is maintained. It is noted that applicants intend to file a terminal disclaimer, however the rejection will be maintained until the terminal disclaimer is filed and found proper.

### ***New Grounds of Objection***

#### ***Claim Objections***

7. Claims 102-106 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. These claims are drawn to biological sample however the claims fail to further limit the structure of the instantly claimed apparatus. Therefore clarification is required to overcome the objection.

#### ***Conclusion***

8. No claims allowed.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na Hines whose telephone number is 571-272-0859. The examiner can normally be reached on Monday-Thursday and alternate Fridays.

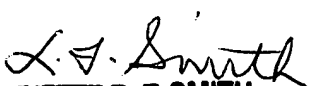
Art Unit: 1645

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on 571-272-0864. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ja-Na Hines

May 22, 2006

  
**LYNETTE R. F. SMITH**  
**SUPERVISORY PATENT EXAMINER**  
**TECHNOLOGY CENTER 1600**